## CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 85888

## **ADMINISTRATIVE DOCUMENTS**

NDA NUMBER 85-888

NOTICE OF APPROVAL  NEW DRUG APPLICATION OR SUPPLEMENT		85-888	
		DATE APPROVAL LETTER ISSUED	
		APR 26 **	
TO:	FROM:	· <del></del>	<del>31.13 - 7 - Q</del>
	ì	Bureau of Drugs	
Press Relations Staff (HFI-40)		20.000 0. 2.000	
	Bureau of Veterinary Medicine		
A 0000		Dure au or vetermary a	redicine
	ENTION		
Forward original of this form for publication only approval has been entered above.	atter approvat letter	nas been issued and	the date of
		<del></del>	
TYPE OF APPLICATION SUPPLEMEN TO CHALLEY ADD	DELLITERMENT	CATEGORY	
MONIGINAL NOA LI TO NOA	MARKET CHE	XHUMAN	VETERINARY
TRADE NAME (or other designated name) AND ESTABLISHED OR	NONPROPRIETARY	NAME (II any) OF DRUG	
Brompheniramine Maleate			
DOSAGE FORM	· · · · · · · · · · · · · · · · · · ·	HOW DISPENSED	
tablet		X RX	□ orc
ACTIVE INGREDIENT(S) (as declared on label. List by established or nonproprietary name		<del></del>	
declared on label.)	iisagispitotary na 	motel and michaels emocal	./+>> it amount is
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Bron	mpheniramine M	laleate 4 mg.	
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NAME OF APPLICANT (Include City and State)	Chuc	mallou Pharmac	outicals Inc
		malloy Pharmac	
	Chromalloy Laboratories, Division		
	5353	Grosvenor Blv	d .
•			
	LOS	Angeles,CA 900	00
	<del></del>		
PRINCIPAL INDICATION OR PHARMACOLOGICAL CATEGORY			
Antihistamine			
COMPLETE FOR	VETERINARY ONLY		<u></u>
ANIMAL SPECIES FOR WHICH APPROVED			
COURT ETE SOO	SUPPLEMENT ONLY		
	JUPPLEMENT UNLI		
CHANGE APPROVED TO PROVIDE FOR		•	
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FORM PR	EPARED BY		
NAME		DATE	
J.M.Ross	į	1	;
		<u></u>	
	PPROVED BY	·	
NAME		DATE	
J. Mever		7	